PRACE POGLĄDOWE
REVIEW ARTICLES

INTERNATIONAL MEDICAL LAW AND ITS IMPACT ON THE UKRAINIAN HEALTH CARE LEGISLATION

MIĘDZYNARODOWE PRAWO MEDYCZNE I JEGO WPŁYW NA AKTY PRAWNE DOTYCZĄCE OCHRONY ZDROWIA NA UKRAINIE

Vitalii Pashkov[1], Larysa Udovyka[2], Hanna Dichko[2]
[1] POLTAVA LAW INSTITUTE OF YAROSLAV MUDRIY NATIONAL LAW UNIVERSITY, POLTAVA, UKRAINE
[2] STATE HIGNER EDUCATIONAL INSTITUTION "ZAPORIZHZHIA NATIONAL UNIVERSITY", ZAPORIZHZHIA, UKRAINE

ABSTRACT

Introduction: The Ukrainian state has an urgent necessity of rapid search for essentially new legal and organizational forms of the healthcare system, reform of the legal regulation of healthcare services provision. In the context of European integration, the advancement of the medical industry reform is closely related to consideration of international standards and norms of health care.

The aim: To study the impact of international medical law on the Ukrainian health care legislation.

Materials and methods: International and Ukrainian regulations and documents on health care were used in the research. System and structural, functional and legal comparative methods as well as systematization, analysis and synthesis were determinative in the research process.

Review: Systematization of international documents on health care was made. The major problems in the Ukrainian health care legislation were determined in terms of their conformity with the international legislative norms. The expediency of the Medical Code adoption was grounded and its structure was defined.

Conclusions: Most health care international acts are ratified by Ukraine and their provisions are implemented in the legislation. Simultaneously, there is a row of problems, which hinder the Ukrainian health care development and place obstacles in the way of European integration. To remove these obstacles, it is expedient to create a codified act – the Medical Code, which would systematize the provisions of the current medical laws and regulations and fill in the existing gaps in the legal regulation of health care.

KEY WORDS: medical law, international medical law, international document, health care, codification of medical law.

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INTRODUCTION

The Ukrainian state has an urgent necessity of rapid search for essentially new legal and organizational forms of the healthcare system, reform of the legal regulation of healthcare services provision. In the context of European integration the advancement of the medical industry reform is closely related to consideration of international standards and norms of health care. Not only new realities bring difficulties but also open up new possibilities in this field. In the final analysis, exercise of the citizens' constitutional right to health care depends on the content and orientation of the medical industry reform. International medical law is of great significance for modernization of the healthcare system and medical law in Ukraine.

THE AIM

The aim of the given article is to study the impact of international medical law on the Ukrainian health care legislation.

MATERIALS AND METHODS

The analysis of scientific sources shows that the subject matter of medical law and separate matters of international medical law were studied by the following scientists, namely Z. Hladun, I. Zohyi, O. Klymenko, V. Pashkov, I. Seniuta, R. Stefanchuk, S. Stetsenko, V. Stetsenko and others. Meanwhile, the issue of international medical law impact on the Ukrainian health care legislation has not been researched in full. System and structural, functional and legal comparative methods as well as systematization, analysis and synthesis were determinative in the research process.

However, most of Ukrainian scientists' articles were devoted to solving only certain problems in healthcare, in particular, such scientific materials covering issues of pharmaceutical activity [1; 2; 3; 4; 5; 6; 7] and fragmental matters in the field of health services [8].

REVIEW AND DISCUSSION

For understanding the impact of international medical law on the national law and legislation, it is worth to address the Constitution of the World Health Organization, which says that the primary objective of the organization shall be the attainment by all peoples of the highest possible level of health. The term "healthy" is understood, as specified in the Preamble of the Constitution, as a state of complete

physical, mental and social well-being and not merely the absence of disease or infirmity [9]. Exactly these provisions of the WHO Constitution are the basis of international medical law and determine its content. The development of the legal provisions which would contribute to improvement of health of all peoples on the planet in a most effective way is the major task of international medical law. International medical law is part of international law which regulates intergovernmental relations on issues of health care and medicine. Proceeding from this, international contracts and conventions, the provisions of which are aimed, first of all, at the improvement of health of peoples in peace-time and, in addition, to health care in case of war should be viewed as the sources for this field of law [10; 93].

The history of development of international legal provisions in health care is closely related to the domestic law aimed at health care of people and attempts to prevent spread of epidemics and infectious diseases. International legal provisions appeared later, their emergence was an objective necessity since separate states were unable to effectively combat epidemics [11; 262]. In the XXth century, with the development of medicine and international law there were plenty of international contracts and documents adopted. Some of them were of a complex character: along with the right of people to life and health care, they regulated some other relations (the Universal Declaration of Human Rights, 1948; the International Covenant on Economic, Social and Cultural Rights, 1966, etc.). Other documents only covered the issues of health care (the Declaration of Alma-Ata, 1978; the Ljubljana Charter on Reforming Health Care, 1996; the Declaration of Lisbon on Rights of the Patient, 1981, etc.).

The international documents on health care can be conditionally systematized by the following groups: 1) acts and documents characterizing the issue of reforming health care (the Declaration of Alma-Ata, the Ljubljana Charter on Reforming Health Care, etc.); 2) acts and documents, which outline the issue of participants' legal status in relations of health care (the Declaration of Lisbon on Rights of the Patient, the European Charter of Patients' Rights, the Declaration on Physician Independence and Professional Freedom, the Declaration on Human Rights and Individual Freedom of Medical Practitioners, the Position Statement on Nurses and Human Rights, etc.); 3) acts and documents, which touch upon specialized issues of medicine and health care (the Declaration on Euthanasia, the Declaration of Sidney (on death), the Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care, the Universal Declaration on the Human Genome and Human Rights, etc.).

The analysis of implementation by Ukraine of the international position papers on reforming health care allow distinguishing a number of unsolved problems, which adversely affect the functioning of the Ukrainian healthcare system and proper exercise by the citizens of their constitutional right to health care. They are as follows:

1. The ethical and deontological constituents of health care are not provided now. Bioethics, which determines morality of human conduct in biological and medical industry and in health care in terms of its conformity to the moral norms and values, is on the initial stage of development. In medical deontology, which is the set of ethics norms and principles of conduct of medical practitioners in professional accomplishments, there are numerous problems in implementation and adherence to these norms and principles. All the stated above adversely affect the activity efficiency of health care institutions and delivery of health care to the population. Some time ago, the Draft Law "On legal framework for bioethics and its ensuring guarantees" No 7625 dated June 8, 2005 was submitted for consideration to the Verkhovna Rada of Ukraine, but it was never adopted.

2. There are considerable difficulties in financing the health care reform. For a long time greater part of the budgetary financial support has been assigned for remuneration of health care institutions' staff and utility costs. There has been a serious funding shortfall for improvement of the material and technical condition of health care institutions and introduction of new treatment methods.

In order to implement the Concept of Health Care Reform ratified by the Order of the Cabinet of Ministers of Ukraine No 1013-r dated November 30, 2016 based on the economic situation and state of the healthcare system in Ukraine the Verkhovna Rada supported the health care reform on second reading and as a whole on October 19, 2017.

According to the Draft Law "On the state financial security of health care services and medications provision" No 6327 [12], the state guarantees payment for health care services and medications provided to patients (introduction of the principle "money follows the patient") fully or partly from the budget. It is important that guarantees should be provided without dependence on any additional criteria to all citizens of Ukraine, foreigners and stateless persons who reside permanently in the territory of Ukraine (first of all, to foreigners in families of Ukrainian citizens, persons formally recognized as refugees or persons in need of complementary protection.

The following provisions of the Law can be referred to as the essential ones: 1) introduction of the concept "package guaranteed by state" (a clearly specified amount of health care services and medications to be paid from the state budget); 2) full payment of medical services and medications for primary, urgent (approximately 80% of citizens' recourses) and palliative health care; partial payment of medical services on the secondary and tertiary levels; 3) payments of medical services and medications by state through the mechanism of public health care sharing; 4) insurance coverage from the state budget; 5) introduction of formal payment sharing for healthcare services delivery to insured persons from other sources in case of partial coverage of services cost; 6) treatment of persons insured in health care institutions of any ownership form; 7) performance of the functions of insurer and single strategic purchaser of health care services by the new central executive body – the National Health Service Ukraine ("NHSU"). The attention should be paid to the Draft Law of Ukraine "On additional financial state guarantees for provision of

health care services and medications to persons, who protect independence, sovereignty and territorial integrity in the anti-terror operation and ensure its performance" No 6328, which provides for state guarantees of full payment of any level treatment for participants of the anti-terror operation ("ATO") [13] so that to admit their contribution and self-sacrifice in defence of Ukraine.

The above-stated and other innovations in medical industry represent a row of important changes both at the legislative level and at the level of health care and legal policies of the Ukrainian state. Firstly, the guarantees of healthcare services provision in general and those in relation to separate categories of persons in particular are expanded; secondly, the state encourages conscious activity and responsibility of citizens in relation to their attitude to own life and health (voluntary healthcare insurance); thirdly, recognition of international clinical directives for the purpose of applying the best world practices of healthcare services provision in Ukraine.

3. Unfortunately, the population's needs in healthcare services in Ukraine are not satisfied. The evidence of this is insufficient financing and non-fulfilment of healthcare programs, namely: the National Social Target Program of Actions Against Tuberculosis for 2012-2016, the National Program of Fighting Against Oncology Diseases for 2007-2016, the State Target Program "Diabetes Mellitus" for 2009-2013, the National Program of Immunoprophylaxis and Protection of People from Infectious Diseases for 2007-2015 [14; 74].

In addition, the concept of the National Social Target Program of Actions Against Tuberculosis for 2012-2016 is still at a draft stage; the National Program of Fighting Against Oncology Diseases for 2007-2016 can only be adopted in 2018.

4. There is a low level of civic education in prophylaxis of diseases and healthy way of life. Currently there are no state-backed programs in this field and mainly public organizations are engaged in outreach. However, according to the statistical figures, civic education and promotion of discarding harmful habits (smoking, overweight, unhealthy diet) can considerably reduce the amount of cardiovascular diseases. Therefore, Ukrainian medicine should aim not only to treat but, first of all, to promote prophylaxis of diseases. However, these provisions remain non-enshrined in the legislation.

In the context of the above-stated group of problems attention should be paid to involvement of public organizations into actions against HIV and tuberculosis, including fulfilment of the state social order of providing health care to people with a limited access to medical services, increase in the level of public awareness, settlement of the problem related to negative attitude of society to patients with tuberculosis and HIV-positive persons and discrimination against them in the healthcare system. The strategy of advocacy, communication and social mobilization, assistance to creation of associations of people affected by these diseases and involving these people in fighting against them needs to be developed and introduced.

5. There is no legislative framework for family medicine. In the Fundamentals of the Legislation of Ukraine, there is Section III, which covers the issues of health care organization in Ukraine. In Articles 35 – 35-5 medical and preventive aid is divided into three types: primary, specialized (secondary) and highly specialized (tertiary) with elucidation of medical services amount provided at each level. But there is no concept of family medicine in the given Section. It can only be found in lower-level regulations – the Concept of Development of Health Care for the Population of Ukraine ratified by the Decree of the President of Ukraine No 1313/2000 dated December 7, 2000. Such a situation adversely affects the development of family medicine as a type of health care provision to the population.

6. The mechanisms of healthcare system management through independence of healthcare institutions are ineffective when managing own resources. Currently in Ukraine healthcare institutions of public and communal ownership cannot freely dispose of their money and mainly follow strict instructions "from superior bodies". This situation adversely affects the efficiency of these institutions functioning. Now the Cabinet of Ministers of Ukraine has initiated the process of reforming healthcare industry, which includes autonomization of health care institutions, simplifies the process of hospital expenditures estimation, and also provides for creation of hospital regions for co-operation of hospitals and local self-government bodies. However, at the legislative level these changes are not enshrined in any law yet.

Thus, the domestic legislation and practice of its implementation in health care are characterized by some problems, their non-conformity to the international provisions and global practices of these provisions implementation. The numerous provisions of medical law adopted during the independence of Ukraine implement the legislative acts in accordance with the requirements of European integration. In some countries of the world – the USA, Italy, Spain, France and others – legal relations in health care are regulated by healthcare codes. Using this positive foreign experience, considerable part of the problem of healthcare legislative support in Ukraine can be solved through adopting of the codified legal act on health care.

In the context of the above said the opinion of I. Seniuta, who grounds the necessity of medical code development and adoption in Ukraine, is timely. She explains the urgency and importance of a codified act creation by the following circumstances: necessity to carry out a complex reform of the domestic healthcare system, including its legislative support as a ground for further transformations; current conformity of a science-based concept to the law-making activity in this field; aspiration for providing an increase of the legal knowledge level of medical practitioners; assistance and consulting provided by lawyers in considering and deciding of so-called "medical cases"; in some cases non-conformity of branch legislation to some laws on health care and medicine; need for clear regulation of medical practitioners and patients' legal status; need for legal regulation of different healthcare systems (state, municipal, private) [15; 7].

Thus, adoption of the Medical Code is necessary for regulation of healthcare legislation in Ukraine and adaptation to the provisions of international and European standards. Harmonization and adaptation of healthcare legislation in Ukraine is a constituent in the process of European integration and legal globalization. There are some positive changes in the Ukrainian health care, namely the adoption of the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care" [16], which provides for the principles of healthcare activity in detail, though it has some gaps. This law is the basis, on which it is expedient to formulate suggestions for the content of the codified act.

For the countries of the Roman-German legal family, where Ukraine belongs to, the traditional structural organization of code is its division into General and Special Parts. The first part contains the basic provisions representing general and common legal provisions for the entire industry, which can be applied to all legal relations in health care. The second part contains the provisions, which are not universal and applied to specialized legal relations in health care.

Thus, the structure of the Medical Code may have the form as follows:

1. Section 1: the principles of medical law and definition of basic concepts.

2. Section 2: human and citizen rights in health care. The following list should be included in this part: the right of a person to qualified medical aid, safe natural environment, safe and healthy terms of labour, participation in law-making activity and management of health care, protection against any illegal forms of discrimination related to the state of health, etc. The legal status of patient should be defined separately, namely the definition of the term as well as patient's rights and obligations should be given, for instance, the right to consent or reject treatment, free choice of practitioner, methods of treatment and healthcare institution, right to obtain information on the state of health and the right to confidentiality of this information, right to receive educational information on healthy life styles, right to have their dignity and religious beliefs respected, right to appeal against wrongful decisions and actions of medical practitioners, healthcare institutions and bodies and right to compensation of damage done to the health.

3. Section III: legal status of medical practitioners. The rights of medical and pharmaceutical practitioners should include the following: execution of medical and pharmaceutical activity in accordance with speciality and qualification; right to proper conditions of professional activity and in-house training; compulsory insurance for the period of professional activity execution for the account of owner of healthcare institution, right to social aid from state, to defence of professional dignity, etc. As well, the given part should provide for the obligations of medical practitioners: to contribute to care and strengthening of people's health, prevention and treatment of diseases, to provide timely and qualified healthcare and medical aid; to provide emergency medical care in case of accidents and other extreme situations; to disseminate scientific and medical knowledge among population and propagandize the healthy way of life; to adhere to the requirements of professional ethics and deontology, protect medical confidentiality; to constantly increase the level of professional knowledge and skill, etc.

4. Section IV: organization of the healthcare system. In this section special attention should be paid to family medicine as it is poorly regulated by legislation, but at the same time it should become the basic vector of development of medical services provision in Ukraine.

5. Section V: health care financing. The major issues, which require legislative revision, are the list of sources for financing health care and definition of certain autonomy for health care institutions in their authority over finances. These problems have been partly settled after the recent adoption of the Law of Ukraine "On making alterations to some legislative acts of Ukraine in relation to improvement of the legislation on issues of healthcare activity" dated April 6, 2017. However, the important innovation of medical insurance introduction has not been enshrined in the Ukrainian legislation, and the Code provisions should change the situation.

6. Section VI: standardization, control and supervision within the framework of healthcare activity. Sanitary and epidemiological welfare of the population, turnover of narcotic drugs and medications should become special objects of supervision and control.

7. Section VII: legal responsibility in medical law and provisions, which refer to other codified acts (The Code of Administrative Offences, Civil Code, Labour Code, Criminal Code).

8. Section VIII: international cooperation in health care – introduction of advanced technologies in treatment and rehabilitation of patients, use of foreign medications and health care reform in accordance with international standards.

The Special part of the Medical Code should include the sections defining the provisions of legal regulation of the following issues: pharmaceutical activity; expert activity; exercise of rights to reproduction and assisted reproductive technologies; blood and its components donorship, transplantation of organs and other anatomical materials; provision of sanitary and epidemic welfare, fight against infectious diseases; psychiatric aid; biomedical experiments on the person; cosmetology, sports medicine and health resort activities.

CONCLUSIONS

Summarizing the above-mentioned provisions, we can make the following conclusions. Most health care international acts are ratified by Ukraine and their provisions are implemented in the legislation. Simultaneously, there is a row of problems, which hinder the Ukrainian health care development and place obstacles in the way of European integration. To remove these obstacles, it is expedient to create a codified act – the Medical Code, which would systematize the provisions of the current medical laws and regulations and fill in the existing gaps in the legal

regulation of health care. Unfortunately, the introduction of international standards to the Ukrainian legislation does not mean that all the provisions will be accomplished in Ukraine indeed (but not in name) due to a lack of organizational or financial resources. Therefore, the primary objective of the processes of reforming the health care industry should be creation of the conditions under which the laws will be carried out and people of Ukraine will be able to exercise their inalienable right to health care in its entirety.

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ADDRESS FOR CORRESPONDENCE
Vitalii Pashkov
Department of Civil, Commercial and Environmental Law,
Poltava Law Institute, Poltava, Ukraine
tel. +380-532-560-148
e-mail. poltava_inst@nulau.edu.ua

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